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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010383

1. Submitter's Identifications:

Tenghi Co., Ltd.
112, Yi-Chung East Road,
Taiping City, Taichung, Taiwan, R.O.C.

Contact:
Mr. Wei-Min Hsieh
General Manager

Date of Summary Preparation: December, 2000.

2. Name of the Device:

Tenghi-Ear thermometer, Model GT-302.

3. Information of the 510(k) Cleared Device (Predicate Device):

Oriental Temp Teller-Infrared Tympanic Thermometer, Model TT-201 (K984497).

4. Device Description:

The Tenghi ear thermometer is a hand held instrument that measures temperature through the opening of the auditory canal.
Operation is based on measuring the natural thermal radiation emitted from the tympanic membrane and adjacent surfaces.

5. Intended Use:

The intended use for the GT-302 ear thermometer is to measure the body temperature through ear canal by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer is in a detachable probe with disposable cover. GT-302 is intended for use of homecare on people of all ages.

Because that all the performances tested are completely within the limit of standard, and all the labeling is provided according to the requirement of standard, the Tenghi-Ear thermometer fall completely within the scope of clause 1 of ASTM E-1965-98 and ASTM E 1104.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Technical Specifications			
Items		*Value*	
		GT-302	***TT-201***
Manufacturer		Tenghi	Oriental
K number			K984497
Display temperature range		34.0°C to 43.0°C (93.2 to 109.4°F)	34.4°C to 41.1°C (93.92°F to 105.98°F)
Operating ambient temperature range		12.0°C to 38.0°C (53.6 to 100.4°F)	14.0°C to 41.0°C (57.2°F to 105.8°F)
Display resolution		0.1°F or 0.1°C	0.1°F or 0.1°C
Temperature scales		°F or °C (User selectable)	°F or °C (User selectable)
Long term storage ranges	Temperature	-20°C ~ 50°C	-20°C ~ 50°C
	Humidity (Max)	95% (noncondesing)	95% (noncondesing)
Display mode		EAR	EAR
Weight (without batteries)		88g	100g
Accuracy for displayed temperature range			
Applicable patient ages		All ages	All ages
Patient temperature range			
Patient < 34.0°C		± 1°C	± 1°C
34.0°C ≤ Patient Temp < 34.4°C		± 0.3°C	± 1°C
34.4°C ≤ Patient Temp < 35.8°C		± 0.3°C	± 0.3°C
35.8°C ≤ Patient Temp < 36°C		± 0.3°C	± 0.2°C
36°C ≤ Patient Temp < 37°C		± 0.2°C	± 0.2°C
37°C ≤ Patient Temp < 39°C		± 0.2°C	± 0.1°C
39°C ≤ Patient Temp < 41°C		± 0.3°C	± 0.2°C
41°C ≤ Patient Temp < 41.1°C		± 0.3°C	± 0.3°C
41.1°C ≤ Patient Temp ≤ 43°C		± 0.3°C	± 1°C
43°C < Patient Temp		± 1°C	± 1°C

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E 1965-98, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

8. Discussion of clinical results.

A comparison study and clinical repeatability testing was performed on the same four ages groups as that of **TT-201 (K984497)**; 0-3 years, 4-10 years, 11-65 years, and > 65 years. Approximately 39% of the patients participating in the study were considered febrile.
The comparison study demonstrated that the Tenghi GT-302 ear thermometer measured ear temperature equivalently to the **Oriental Ear thermometer TT-201** in all age groups.

9. Conclusions

The Tenghi-ear thermometer, GT 302, has the same intended use and technological characteristics as the cleared device **TT-201 (K984497)**. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Tenghi Company Limited
C/O Mr. Tony C. S. Chang
Wincent Consultant Company Limited
5, Alley 5, Lane Cheng Hsing
Chung Ching Road Pei Tun District
Taichung,
CHINA (TAIWAN)

Re: K010383
Trade/Device Name: Temp Scan/GT-302 (Ear Thermometer)
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: January 3, 2001
Received: February 8, 2001

Dear Mr. Chang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010383
Device Name: Temp Scan / GT-302 (Ear Thermometer)

Indications For Use:

The intended use for the Temp Scan / GT-302 is to measure the body temperature through the ear canal by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer is in a detachable probe with probe cover. Temp Scan / GT-302 is intended for use on people of all ages.

Patricia Cucinotta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010383